PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D **2 8 APR 2006**

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Applicant's or agent's file reference C/2BN50/MvZ/1	**FOR FURTHER ACTION**	See Form PCT/IPEA/416

International application No. PCT/NL2005/000091	International filing date *(day/month/year)* 07.02.2005	Priority date *(day/month/year)* 06.02.2004

International Patent Classification (IPC) or national classification and IPC
INV. G06F19/00

Applicant
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1.   This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2.   This REPORT consists of a total of 7 sheets, including this cover sheet.

3.   This report is also accompanied by ANNEXES, comprising:

   a. ☒   *sent to the applicant and to the International Bureau)* a total of 5 sheets, as follows:

   ☐   sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

   ☒   sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐   *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))   , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4.   This report contains indications relating to the following items:

   ☒ Box No. I   Basis of the report

   ☐ Box No. II   Priority

   ☐ Box No. III   Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

   ☐ Box No. IV   Lack of unity of invention

   ☒ Box No. V   Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   ☐ Box No. VI   Certain documents cited

   ☐ Box No. VII   Certain defects in the international application

   ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 18.01.2006	Date of completion of this report 28.04.2006

Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Abbing, R Telephone No. +31 70 340-4069

Box No. I   Basis of the report

1. With regard to the **language**, this report is based on

    ☒   the international application in the language in which it was filed

    ☐   a translation of the international application into , which is the language
    of a translation furnished for the purposes of:

        ☐   international search (under Rules 12.3(a) and 23.1(b))
        ☐   publication of the international application (under Rule 12.4(a))
        ☐   international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

    Description, Pages

    1-20   as originally filed

    Claims, Numbers

    1-28   received on 18.01.2006 with letter of 18.01.2006

    Drawings, Sheets

    1/12-12/12   as originally filed

    ☐   a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐   The amendments have resulted in the cancellation of:
        ☐   the description, pages
        ☐   the claims, Nos.
        ☐   the drawings, sheets/figs
        ☐   the sequence listing *(specify)*:
        ☐   any table(s) related to sequence listing *(specify)*:

4. ☒   This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
        ☐   the description, pages
        ☒   the claims, Nos. 1-28
        ☐   the drawings, sheets/figs
        ☐   the sequence listing *(specify)*:
        ☐   any table(s) related to sequence listing *(specify)*:

    *   *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V   Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-4,6-10,12,14,15,17,18,23
	No:	Claims	1,5,11,13,16,19-22,24-26
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-26
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item I
Basis for the opinion, amendments considered to go beyond the disclosure of the application as filed (Rule 70.2(c) PCT)

The amendments filed with the International Bureau under Article 19(1) PCT introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 19(2) PCT. The amendments concerned are the following:

Claim 1 now reads (lines 18 - 21, amendments are underlined):
"- a processor configured so as to load from the connected portable electronic storage device either the first of the second computer program depending on the type of data processing device and executing the same, ..."

The addition of the conditional automatic loading of one of two possible computer programs by the processor depending on the type of processing device implicitly necessitates the presence of a detection logic to determine the type of processing device as well as a detection logic to determine the corresponding computer program to be loaded.

Neither of these detection logics can be found in the basis for the amendments as provided by the applicant (claim 4) or in the whole application as filed. The subject-matter of newly filed claim 1 (and dependent claims 2 - 25 and independent claims 27 & 28) therefore goes beyond the disclosure of the application as filed, thus violating Article 19(2) PCT.

Amended claim 26 now explicitly includes the condition that either the first or the second computer program stored on the portable storage device can run on the processor of the data processing device.

This very general condition is also not derivable from the basis for the amendments as provided by the applicant (claim 4) or from the application as a whole. The subject-matter of newly filed claim 26 therefore also goes beyond the disclosure of the application as filed, thus violating Article 19(2) PCT.

Following Rule 70.2(c) PCT, the following opinion is based on the application documents as originally filed (i.e. claims 1 - 26).

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1   Reference is made to the following documents:
   D1 : US 2002/162009 A1 (SHMUELI SHIMON ET AL) 31 October 2002
   D2 : WO 03/079183 A (JAMES, BARRY, EDMUND) 25 September 2003
   D3 : WO 03/046827 A (LIBERATE SOFTWARE LIMITED; KENDON, MICHAEL) 5
      June 2003
   D4 : WO 03/040864 A (GRUSHKA, AMOS) 15 May 2003

2   INDEPENDENT CLAIMS 1, 24, 26
   The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

2.1   Document D1 discloses (see abstract and page 4, line 29 - page 5, line 11) a system comprising:
- a portable memory (storage) device containing at least one software package and associated data, the storage devices being able to be connected to a computer (data processing device) by means of a releasable connection (I/O port),
- a computer (data processing device) comprising a n interface for connecting the portable memory device,
   the computer comprising
- a processor which is able to run the application software package (computer program) from the memory device (i.e. to load the computer program from the memory device and execute the program), the application software using, i.e. adding or modifying the data stored on the connected memory device.
- a display device (screen) for displaying data.

   The nature of the data, stored on the memory device and processed by the

application, does not have any technical effect on the described system. However, D1 even explicitly mentions that the data might include medical records (see page 14, line 30).

The subject-matter of claim 1 can therefore not be regarded as new (Article 33(2) PCT).

2.2 Document D2 discloses:
- a portable storage device comprising an interface (e.g. a USB memory device, see figure 2A), on which information as well as software is stored (see paragraphs [0005], [0009] & [0026] and figures 3A & 3B, steps 106, 108, 122 & 124).
- a host (data processing device), which comprises a suitable I/O port for connecting the portable storage device (see paragraphs [0027] & [0028],
  the host also comprising a processor (CPU),
  which loads and executes the software on the memory device upon interface, i.e. when the portable storage device is connected to the host [see paragraph 0029],
  the software using, i.e. accessing or updating the data on the storage device (see e.g. paragraphs [0038] & [0049])

The nature of the data accessed does not have any technical effect on the disclosed system, and the system as described in claim 1 of the application can therefore not be regarded as new (Article 33(2) PCT) with respect to the content of D2, either.

2.3 The above objections are, *mutatis mutandis*, also brought forward against the independent claims 24 & 26, which consequently also do not fulfill the requirements of Article 33(2) PCT.

2.4 Documents D3 and D4 also disclose systems technically comparable to the systems as described by D1 and D2, and consequently must be seen as equally relevant concerning the question of novelty and/or inventive step of the independent claims.

3 Even if the technical terms used in the claims could lead to slightly different interpretations, this would still not render the above mentioned claims 1, 24 & 26 inventive in the sense of Article 33(3) PCT with regard to the content of each of the

documents D1, D2 D3 or D4, taken alone, as these interpretations lie well within the capabilities of the person skilled in the art.

4   DEPENDENT CLAIMS 2-23, 25
Dependent claims 2-23, 25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see cited passages of D1, D2, D3 and/or D4.

1

International application PCT/ NL2005/000091

Enclosure to letter dated 18-01-2006

EPO - DG 1

19. 01. 2006

(65)

PROPOSED CLAIMS

5   1. System for storing and exchanging medical
data <u>representative of the health of an individual</u>, the
system comprising:
         - a plurality of portable electronic storage devices,
10   each storage device comprising an interface and one or more
data carriers on which are stored medical data representative
of the health of at least one individual, a <u>first</u> computer
program <u>and a second computer program</u>;
         - a data processing device comprising:
15   - a second interface for connecting the data
processing device to at least one of the portable electronic
storage devices,
         - a processor configured so as to load from the
connected portable electronic storage device <u>either the first</u>
20   <u>or the second</u> computer program <u>depending on the type of data</u>
<u>processing device</u> and executing the same, the loaded
computer program including instructions that cause the
processor to process the medical data stored on the portable
storage device, said processing including reading, <u>adding and</u>
25   <u>modifying</u> medical data stored on the connected portable
electronic storage device;
         - a display device for displaying said processed
medical data;
<u>wherein the first computer program is operable so as to</u>
30   <u>exchange medical data with a data processing device of a</u>
<u>first type en the second computer program being operable so</u>
<u>as to exchange medical data with a data processing device of</u>
<u>a different type.</u>

AMENDED SHEET

2

2. System as claimed in claim 1, wherein the medical data include text data and graphical data, for instance X ray plots, scans plots or electro-cardiograms.

3. System as claimed in any of the preceding claims,
5   wherein on the electronic storage device graphical data representative of the appearance of the individual is stored and wherein the processor is programmed so as to load the graphical data from the connected electronic storage device and to display the data representative of the appearance of
10 the individual on the display device of the processing device so as to enable positive identification of the individual.

4. System as claimed in any of the preceding claims, wherein the electronic storage device is configured so as to provide access code protected access to the medical data
15 stored thereon, wherein, depending on the access code, reading, adding and/or modifying rights are conferred for predefined subsets of medical data only.

5. System as claimed in claim 4, wherein one of the predefined subsets of medical data is formed by emergency
20 medical data.

6. System as claimed in claim 1, comprising a first portable electronic storage device being configured so as to store thereon medical data in a first data format and a second portable electronic storage device being configured so
25 as to store thereon medical data in a second data format, different from the first format.

7. System as claimed in claim 6, wherein on the first portable electronic storage device a first computer program is stored capable of having processed medical data in
30 the first format, while on the second portable electronic storage device a second computer program is stored capable of having processed medical data in the second data format.

AMENDED SHEET

3

8. System as claimed in any of the preceding claims, wherein access to the medical data on the electronic storage device is protected by an access code, preferably a password.

9. System as claimed in claim 8, wherein a first
5   user or group of users has data reading rights only.

10. System as claimed in claim 8 or 9, wherein a second user or second group of users has reading and adding rights only.

11. System as claimed in claim 8, 9 or 10, wherein
10   a third user or third group of users has reading, adding and modifying rights of medical data stored or to be stored on the electronic storage device.

12. System as claimed in any of claims 9-11, wherein the reading, adding and/or modifying rights are for a
15   predefined subset of medical data only.

13. System as claimed in any of the preceding claims, wherein computer program is operable so as to permit the addition of a new user or group of users only after receiving the correct access code of said individual.

20   14. System as claimed in any of the preceding claims, wherein the computer program is operable so as to permit access to a predefined portion of the medical data only after receiving the correct access code of said individual.

25   15. System as claimed in any of the preceding claims, wherein the processing device includes an entering device for entering data into the computer device and storing the entered data on the electronic storage device.

16. System as claimed in any of the preceding
30   claims, wherein the processing device is a mobile phone and the electronic storage device is an external storage medium that can be connected to the mobile phone.

17. System as claimed in any of the preceding

4

claims, wherein the processing device is a mobile phone and the electronic storage device is an internal storage medium contained in the mobile phone.

18. System as claimed in any of the preceding claims, wherein the data processing device is a personal computer.

19. System as claimed in any of the preceding claims, wherein a portable electronic storage device is configured so as to be implanted in a person.

20. System as claimed in any of the preceding claims, wherein the electronic storage device comprises a positioning system.

21. System as claimed in any of the preceding claims, wherein the electronic storage device is configured so as to store non-medical personal data.

22. System as claimed in any of the preceding claims, wherein at least part of the medical and/or health data stored on the electronic storage medium is encrypted.

23. System as claimed in any of the preceding claims, wherein the first and second interface are wireless communication devices so as to provide a wireless connection between the portable electronic storage device and the data processing device.

24. System as claimed in any of the preceding claims, wherein the first and second interface are wired communication devices so as to provide a wired connection between the portable electronic storage device and the data processing device.

25. System as claimed in any of the preceding claims, wherein the computer program is operable so as to provide text on the display device in one of a plurality of languages, said one language being user selected from a pre-stored list of languages

26. Portable electronic storage device for

5

storing and exchanging medical data with a data processing

device having an interface, a processor and a display device,

wherein the portable electronic storage device comprises a

data carrier on which is stored medical data representative

5   of the health of at least one individual, <u>a first and a</u>

<u>second</u> computer program, <u>wherein either of the computer</u>

<u>programs</u>, when run on said processor, causes said processor

to process the medical data stored on the data carrier, said

processing including reading, adding and/or modifying medical

10   data stored on the connected portable electronic storage

device, and displaying said processed data on the display

device.

27. Portable electronic storage device as claimed

in claim 26 and any of claims 1-25.

15   28. Method of storing and exchanging medical data

in the system as claimed in any of claims 1-25.

AMENDED SHEET